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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/753,717

01/08/2004

Simon Jon Dunmore

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6273

37903

7590

07/24/2007

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT

PAPER NUMBER

1649

MAIL DATE

DELIVERY MODE

07/24/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/753,717	<b>Applicant(s)</b> DUNMORE ET AL.	
	<b>Examiner</b> Robert C. Hayes, Ph.D.	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |                                                                                                            |                                                                                         |
|------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                                           | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____                                                |

**DETAILED ACTION**

***Response to Amendment***

1. The amendment filed 4/20/07 has been entered.
2. The rejection of claims 1-19 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 5,763,200 is withdrawn due to the submission of a terminal disclaimer.
3. Applicant's arguments filed 4/20/07 has been fully considered but they are not deemed to be persuasive.
4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 5, 7-11, 13, 15-16 & 18 are rejected under 35 U.S.C. § 103 as being unpatentable over Inoue et al. (IDS Ref #I) or Moore et al. (IDS Ref #J), in view of Yamada et al. (IDS Ref #O), for the reasons made of record in Paper No: 20070110, and as follows.

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Applicants argue on pages 6-8 of the response that “the cited references fail to teach that compounds binding to the SSTR-5 receptor are the preferred compounds as none of Inoue, Moore or Yamada teach the investigation of SSSTR-5 ligand/receptor in particular”. In contrast to Applicants’ assertions, nothing in the current claim language requires an “advantage” to be used as an active step to distinguish compounds that preferentially bind to only “a somatostatin type-5 receptor”. For example, no K<sub>d</sub> values to be assayed to distinguish SSTR-1 binding from SSTR-2 binding from SSTR-3 binding from SSTR-4 binding from SSTR-5 binding are recited in the claims, etc. Moreover, the ligand somatostatin clearly “is determined to *be able to* bind to a somatostatin type-5 receptor...”, by definition, because otherwise no somatostatin receptor of any type would be present. Therefore, Applicants’ arguments are not persuasive, for the reasons made of record.

In summary, Inoue et al. teach a method of determining the ability of a compound (i.e., somatostatin, which by definition binds to the somatostatin type-5 receptor) to inhibit amylin release from amylin-secreting rodent pancreas cells (i.e., as it relates to claims 1-2, 10-11, 13, 15-16 & 18). The pancreatic cells are incubated with the amylin release stimulators, glucose or arginine, under conditions in which amylin secretion is induced, followed by addition of somatostatin, in which amylin secretion is then inhibited by 40-70% (pg. 251, Abstract and pg. 252, Figure 1A and Table 1). However, Inoue et al. do not teach determining the ability of a compound to compete against ligand binding to SSTR-5, in which at least the ligand or compound (i.e., agonist) is detectably labeled.

Moore et al. teach a method of determining the ability of a compound (i.e., somatostatin, which by definition binds to the somatostatin type-5 receptor) to inhibit amylin release from amylin-secreting pancreas cells (i.e., HIT T15  $\beta$ -islet cells; as it relates to claims 1-2 & 10-11). The pancreatic cells are incubated with the amylin release stimulators, glucose plus arginine, under conditions in which amylin secretion is induced, followed by addition of somatostatin, in

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which amylin secretion is subsequently inhibited by 40% (pgs. 5-6 and Figure 5B). However, Moore et al. do not teach determining the ability of a compound to compete against ligand binding to SSTR-5, in which at least the ligand or compound (i.e., agonist) is detectably labeled.

Yamada et al. teach a method for obtaining preparations containing SSTR-5 that are used to determine the ability of compounds to bind to SSTR-5 (i.e., the first step of the method of claim 1). The rank potency of somatostatin analogs are: somatostatin-28>somatostatin-14 >>RC-160>SMS201-995 for human SSTR-5, based on competition studies (pg. 844, Abstract). Yamada further teach that after obtaining a preparation of cell membranes (i.e., as it relates to claims 1 & 3), which contains SSTR-5 (i.e., COS1 cells expressing SSTR-5; as it relates to the equivalent transfected cells of claims 5 & 7), incubation with a detectably labeled ligand (i.e., [<sup>125</sup>I-Tyr<sup>11</sup>]-somatostatin-14; as it relates to claims 8-9) in the presence of the compounds somatostatin-14, somatostatin-28, SMS201-995 and RC-160 compete against labeled somatostatin-14 for binding to SSTR-5. However, Yamada do not teach obtaining amylin-secreting pancreatic cells in their method (i.e., the second step of claim 1).

It would have been obvious to one of ordinary skill in the art at the time of the Applicants' invention to use the method of Yamada et al. for determining binding compounds for SSTR-5, followed by evaluation of the biological effects of SSTR-5 compounds using the method of Moore or Inoue to inhibit amylin secretion in pancreatic cells, because agonists have similar functional activities as native ligands by definition, and because Yamada specifically suggest that use of somatostatin subtypes (e.g., SSTR-5 agonists) should reveal the molecular basis for somatostatin function, which includes exocrine and endocrine function (i.e., amylin inhibition) in the pancreas, pituitary and GI tract (see pgs. 851 and 845).

6. Claims 1-11, 13, 15-16 & 18 are rejected under 35 U.S.C. § 103 as being unpatentable over Inoue et al. or Moore et al., in view of Yamada et al., as applied to claims 1-3, 5, 7-

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11, 13, 15-16 & 18 above, and further in view of Hoyer et al. (IDS Ref #H), for the reasons made of record in Paper No: 20070110, and as follows.

The rejection is maintained for similar reasons discussed above in *pp* #5. Therefore, Applicants' arguments on pages 8-9 of the response are also not persuasive for the reasons made of record.

In summary, Inoue et al., Moore et al. and Yamada et al. are as described above. However, none of these three references teach that rodent olfactory bulb contain SSTR-5 receptors.

Hoyer et al. teach numerous sources for cell preparations that contain SSTR-5 in Table 3 (pg. 447) that includes rat olfactory bulb (as it relates to claims 4 & 6), as well as CHO-K1 cells transfected with SSTR-5 (pgs. 444-445 and Fig. 2; as it relates to claims 5 & 7). However, Hoyer do not specifically teach subsequent inhibition of amylin secretion in pancreatic cells, even though they do disclose that somatostatin inhibits the pancreatic-associated hormones insulin and glucagon with different pharmaceutical profiles (pg. 441, 2nd column).

It would have been obvious to one of ordinary skill in the art at the time of the Applicants' invention to use Hoyer's cell preparations (i.e., rat olfactory bulb and CHO-K1/SSTR-5 cells; as it relates to claims 4-7), or Hoyer's somatostatin agonists (pg. 443, Table 2) in the method of Yamada as described above, because different tissues express different levels of SSTR-5 and thus provides an additional source of cell/membrane preparations for carrying out Yamada's method using competing SSTR-5 binding compounds when combined with the methods of Inoue or Moore for inhibiting amylin secretion, as discussed above.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (571) 272-0841. The fax phone number for this Group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.  
July 20, 2007

ROBERT C. HAYES, PH.D.  
PRIMARY EXAMINER